IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
Clarksburg

ASTRAZENECA AB and **ASTRAZENECA PHARMACEUTICALS LP,**

Plaintiffs,

v.

CIVIL ACTION NO. 1:22-CV-35
Judge Bailey

MYLAN PHARMACEUTICALS, INC. and **KINDEVA DRUG DELIVERY L.P.,**

Defendants.

FINAL JUDGMENT ORDER

The trial in the above-styled matter was initially set for December 13, 2022. On December 12, 2022, the parties filed a Stipulation of Liability [Doc. 225] stating that "the only remaining liability issue relates to Defendants' defense and Counterclaim that the '558 patent is invalid," which Defendants stated that, subject to their rights to appeal, they "consent to the entry of judgment in this action that the Asserted Claims are not invalid based on the Court's construction of the term 'pharmaceutical composition,'" and that, subject to their rights to appeal, Defendants "consent to the entry of judgment in this action that the Asserted Claims are infringed under 35 U.S.C. § 271(e)(2) based on the Court's Summary Judgment Order."

Thereafter, this Court canceled the trial and scheduled oral argument with respect to remedies. On December 14, 2022, this Court heard oral argument. After considering both sides arguments, **IT IS HEREBY**,

ORDERED AND ADJUDGED that, in light of defendants' stipulation of infringement and validity, Final Judgment shall be and the same is hereby entered in favor of plaintiffs AstraZeneca AB and AstraZeneca Pharmaceuticals LP and against defendant Mylan Pharmaceuticals, Inc. and Kindeva Drug Delivery L.P., finding that defendants have infringed claims 1, 3, 4, 7, and 12 of the '558 patent;

ORDERED AND ADJUDGED that Final Judgment shall be and the same is hereby entered in favor of plaintiffs and against defendants on all counterclaims alleging, and seeking declarations of non-infringement and invalidity of the '558 patent;

ORDERED that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval by the Untied States Food and Drug Administration of Mylan's Abbreviated New Drug Application ("ANDA") No. 211699 shall be a date which is not earlier than the expiration date of the '558 patent, including any extensions thereof; and it is further

ORDERED that, pursuant 35 U.S.C. § 271(e)(4)(B), defendants, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, are **ENJOINED** until **July 29, 2023**, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the products which are the subject of ANDA No. 211699; and it is further

ORDERED that, pursuant to 35 U.S.C. § 283, defendants, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, are **ENJOINED** until the expiration date of the '558 patent, including all extensions thereof through **July 29, 2023**, from engaging in the commercial manufacture, use, offer

for sale, or sale within the United States, or importation into the United States, of the products which are subject of ANDA No. 211699;

ORDERED that, pursuant to this Court's equitable power, the effective date of any final approval of ANDA No. 211699 shall be a date that is not earlier than **July 29, 2023**, the latest date of expiration of the '558 patent, including AstraZeneca's period of pediatric exclusivity; and

ORDERED that AstraZeneca provide a copy of this Judgment to the U.S. Food and Drug Administration within two (2) business days of this Judgment.

The Clerk is **DIRECTED** to enter judgment in favor of plaintiffs and against defendants. It is further that the above-styled case be **STRICKEN** from the active docket of this Court.

It is so **ORDERED**.

The Clerk is directed to transmit copies of this Order to all counsel of record.

DATED: December 15, 2022.

JOHN PRESTON BAILEY
UNITED STATES DISTRICT JUDGE